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| APPLICATION NO.                 | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|-------------|----------------------|---------------------|------------------|
| 09/908,994                      | 07/17/2001  | John Shigeura        | 4470                | 8729             |
| 20995                           | 7590        | 05/25/2007           |                     |                  |
| KNOBBE MARTENS OLSON & BEAR LLP |             |                      | EXAMINER            |                  |
| 2040 MAIN STREET                |             |                      | SISSON, BRADLEY L   |                  |
| FOURTEENTH FLOOR                |             |                      | ART UNIT            | PAPER NUMBER     |
| IRVINE, CA 92614                |             |                      | 1634                |                  |
|                                 |             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|                                 |             |                      | 05/25/2007          | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/908,994 | <b>Applicant(s)</b><br>SHIGEURA ET AL. |  |
|                              | <b>Examiner</b><br>Bradley L. Sisson | <b>Art Unit</b><br>1634                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 February 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 21-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,593,838 (Zanzucchi et al.) in view of US Patent 5,607,646 (Okano et al.) and US Patent 5,962,228 (Brenner).
5. For convenience, claim 21, the sole independent claim, is reproduced below.

21. **(Previously presented)** A method for isolating one or more different-sequence polynucleotides from a mixture, the method comprising:

(a) flowing the mixture through a flow path containing a plurality of solid supports which are located in series in the flow path, such that the mixture flows serially through each of the plurality of solid supports, each support having bound thereto a sequence-specific capture agent complementary to a different-sequence polynucleotide, under conditions effective to specifically bind different-sequence polynucleotides to corresponding sequence-specific capture agents on one or more of the supports,

(b) after said specific binding, releasing bound polynucleotides from a selected support by altering a physical property of that support while leaving unaltered the same physical property of at least one other of the supports, wherein the physical property is temperature, and wherein said releasing is accomplished by heating a first solid support; and

(c) eluting the released polynucleotides through the flow path such that the eluted polynucleotides can be isolated in separated form.

6. For purposes of examination claim 10 has been interpreted as encompassing the isolation of from one to an infinite number of nucleic acid sequences, and that at a minimum, two different capture moieties are to be present and are bound at two different locations on a support that can virtually any shape but can act as a flow path for a mixture of nucleic acids capable of flowing.

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7. Zanzucchi et al., disclose a method of isolating one or more different-sequence polynucleotides from a mixture. At column 2, bridging to column 3, Zanzucchi et al., disclose using an array of wells in serial fluid connection, through which a sample is caused to pass.
8. Zanzucchi et al., column 5, fourth paragraph, teaches that the device may comprise thin film transistors so to provide power to the wells via leads and electrodes.
9. Zanzucchi et al., column 8, teaches that beads can be placed in one or more of the wells, and that the beads can have bound to their surface DNA material, e.g., probe or capture sequences.
10. Zanzucchi et al., column 2, teach explicitly of using the device to generate PCR fragments that can be subject to an assay/analysis. At column 9, first paragraph, Zanzucchi et al., speak explicitly of having incorporated heating and cooling means in the well as well as the use of pumping means to move a sample from one well to another. At column 10, Zanzucchi et al., speak of conducting PCR wherein the primer is immobilized to a solid support. Such a teaching speaks directly to the presence of a heating/cooling means for the second well, else, strand dissociation and reannealing would not be able to take place.
11. Zanzucchi et al., column 10, fourth paragraph, teach that all of the wells in each module are connected together via one or more channels. Accordingly, one can cause the sample mixture to flow in a serial manner through each of the plurality of solid supports.
12. Zanzucchi et al., column 10, teaches that the probes may be synthesized directly into a well.

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13. Zanzucchi et al., column 8, fourth paragraph, teaches explicitly that “[a]dditional devices can be built into the wells.” Such a showing clearly speaks to the further adaptation of the device so to accommodate any structure and arrangement the ordinary artisan desires.

14. Okano et al., column 2, second and fifth paragraphs, teaches:

It is an objective of the present invention to provide a polynucleotide capturing chip capable of simultaneously capturing a plurality of target polynucleotides, to provide a method for detecting a plurality of polynucleotides using the same and to provide a method for separating a plurality of target polynucleotides

[E]ach cell of the polynucleotide capturing chip to be used as the polynucleotide capturing support also functions as an electrode for eluting the target polynucleotides, wherein the electric fields applied to such electrodes each with a plurality of immobilized probes can be switched over one by one to elute and separate a plurality of the target polynucleotides.

15. Okano et al., third column, bridging to column 4, teaches that the combination of heating and reversal of electric field can be used to achieve elution of specifically captured sequences from specific wells/regions of the chip, while retaining the captured polynucleotide bound at other positions.

16. While Okano et al., uses a single substrate, it has been fashioned into a series of cells, and the temperature and electric field of each is under control, thereby allowing for individual, serial, or simultaneous elution of released polynucleotides.

17. Brenner, column 15, teaches that an array can be fashioned from a plurality of microparticles that are brought into contact with a support. And that the microparticles may comprise tag complements.

18. In view of the teachings of the prior art of record, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the microparticles

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of Brenner in the individual cells of the array of Okano et al., with the series of wells/array of Zanzucchi et al., whereby the device would be used in a polynucleotide assay whereby specific binding reactions can take place at selected supports and eluted from same, and that the mixture would flow in a serial fashion through each of the solid supports. In view of the well-developed state of the art, said ordinary artisan would have had a most reasonable expectation of success. Therefore, and in the absence of convincing evidence to the contrary, claims 21-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,593,838 (Zanzucchi et al.) in view of US Patent 5,607,646 (Okano et al.) and US Patent 5,962,228 (Brenner).

Response to argument

19. Argument is presented at page 8 of the response received 14 February 2007, hereinafter the response, that the method of Okano teaches away for the claimed invention in that heating is performed at multiple locations. This argument has not been found persuasive, as applicant is arguing the references individually, and not taking into account the combined disclosure of all of the cited works.

20. The primary reference, Zanzucchi et al., teach the individual heating, or cooling, of separate wells in their array. Accordingly, if the ordinary artisan used each well of Zanzucchi et al., to contain a separate probe, and to alter the temperature of one well, it would leave unchanged the temperature of the other, the hybridized nucleic acids bound therein.

At page 9, applicant presents argument that while Zanzucchi et al., does teach heating that is for performing an enzymatic reaction. This argument has not been found persuasive, as the "enzymatic reaction" being performed is Zanzucchi et al., is none other than PCR. Here, the

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heating step is to cause double stranded DNA to dissociate. This is the very feature that applicant is relying upon to cause the target polynucleotide to dissociate from the probe. Clearly, one of ordinary skill in the art has common sense and would be able to recognize the usefulness of heating to dissociate specific binding reactions between complementary polynucleotides, and be able to use same in.

As set forth in *KSR International v. Teleflex Inc., et al.*, (US Supreme Court, April 2007):

Under the correct analysis, any need or problem known in the field and addressed by the patent can provide a reason for combining the elements in the manner claimed.

It is common sense that familiar items may have obvious uses beyond their primary purposes, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle.

21. In response to applicant's arguments against the references individually (pages 8-10 of the response), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

22. At pages 10-11, applicant's representative asserts first that no motivation has been provided and then asserts that the motivation provided is "inadequate." Applicant's second argument is taken to refute their first position that no motivation has been provided.

23. Argument is presented that the teachings of Okano et al., are not combinable with the teachings of Brenner (or Zanzucchi et al.?) in that there is no teaching of how to heat the first support without heating the second support. This argument has not been found persuasive towards the withdrawal of the rejection for as shown above, Zanzucchi et al., teach heating individual wells in their array of wells. Clearly, the heating of one well in an array does not heat



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the other well. Consequently, the placement of probes in a well, and hybridizing target to same, and then dissociating said target from said probe, as was done between the target/template and extended primer, meets this very limitation.

24. At page 13 of the response argument is made that the rejection of claims under 103(a) must be withdrawn given applicant's application of the *Graham v. John Deere Co.* test.

25. The above argument has been fully considered and has not been found persuasive as applicant's representative is seemingly seeking to apply some rigid, formulistic application of the *Graham v. Deere* analysis. As set forth in *KSR International v. Teleflex Inc., et al.*, (US Supreme Court, April 2007):

Rigid preventative rules that deny recourse to common sense are neither necessary under, nor consistent with, the Court's case law.

26. While the prior art has not been found to suggest specific shapes of the channel, nor the structure of the flow path, such elements are not deemed to rise to the level of a patentable distinction, but rather, constitute obvious design choices. Similarly, the choice of material used to fashion the support is a matter of obvious design choice as they were known in the art and no unexpected result is attributable to their use here. In support of this position, attention is directed to page 10, first full paragraph, of the specification, which teaches that the support can be any of the "materials used in standard electrophoresis or chromatographic DNA separation methods." *In re Hopkins* 145 USPQ 140 (CCPA, 1965).

27. For the above reasons, and in the absence of convincing evidence to the contrary, claims 21-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,593,838 (Zanzucchi et al.) in view of US Patent 5,607,646 (Okano et al.) and US Patent 5,962,228 (Brenner).

***Conclusion***

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

29. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

31. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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32. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/  
Primary Examiner  
Art Unit 1634

BLS